

WHAT IS CLAIMED IS:

1. A process for deforming a medical device including a shape memory alloy element having a martensite deformation temperature (M_d), wherein the element includes a restrained shape and a deployed shape for use in a mammalian body, comprising:

- 5 heating the shape memory alloy element to a temperature at or above M_d ;
at least partially deforming the element into the restrained shape; and
applying a force to maintain the element in the restrained shape.

2. The process of claim 1, further comprising positioning the medical device including the element at least partially inside a hollow delivery system to hold the element in the restrained shape.

3. The process of claim 2, further including cooling the medical device inside the hollow delivery system to room temperature.

4. The process of claim 1, wherein the shape memory alloy is in an austenitic state at room temperature of about 22 degrees C.

5. The process of claim 1, wherein the shape memory alloy includes nickel and titanium.

6. The process of claim 1, wherein the medical device includes a stent.

7. The process of claim 1, wherein the step of at least partially deforming the element into a restrained shape does not generate stress-induced martensite.
8. The process of claim 1, wherein the hollow delivery system includes a catheter.
9. The process for deforming a medical device of claim 1, wherein the heating is performed by a light source.
10. The process for deforming a medical device of claim 1, wherein the heating is performed by heated fluid.
11. The process for deforming a medical device of claim 1, wherein the heating is performed by ultrasonic vibration.
12. The process for deforming a medical device of claim 1, wherein the heating is performed by a current source connected to the shape memory alloy element.
13. The process for deforming a medical device of claim 1, wherein the heating is through rolling nitinol stent on a warm plate.
14. A medical device and delivery system, comprising:
a shape memory alloy element having a restrained shape, a deployed shape and an associated M_d temperature, wherein the shape memory alloy element is deformed at or above M_d ; and

a hollow delivery system holding the at least partially deformed shape memory alloy element in its restrained shape.

15. The medical device and delivery system of claim 14, wherein the shape memory alloy includes nickel and titanium.

16. The medical device and delivery system of claim 14, wherein the medical device includes a stent.

17. The medical device and delivery system of claim 14, wherein the delivery system includes a catheter.

18. The medical device and delivery system of claim 14, wherein the shape memory alloy does not generate stress-induced martensite from being at least partially deformed into a restrained shape.

19. The medical device and delivery system of claim 14, wherein the shape memory alloy is a tubular member with proximal and distal ends and the restraint is secured around the shape memory alloy in its deformed configuration.

20. The medical device and delivery system of claim 14, wherein the shape memory alloy is for use within a mammalian body or in close proximity to the mammalian body such that the device is at mammalian body temperature.

21. The medical device and delivery system of claim 14, wherein the mammalian body temperature is about 35 to 40 degrees C.

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22. The medical device and delivery system of claim 14, wherein the shape memory alloy has an austenite start temperature (A_s), an austenite finish temperature (A_f), and a martensite deformation temperature (M_d).

23. The medical device and delivery system of claim 22, wherein the shape memory alloy includes the martensite deformation temperature (M_d) of about 50 degrees C or more above the austenite finish temperature (A_f).

24. The medical device and delivery system of claim 1, wherein the shape memory alloy is in an austenitic state at room temperature of about 22 degrees C.

TO THE "PATENT"